

MEDICAL RECORD	MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Attach to NIH-2514-2, Consent to Participate in a Clinical Research Study
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INSTITUTE: National Institute of Child Health and Human Development

STUDY NUMBER: 00-CH-0160 PRINCIPAL INVESTIGATOR: Constantine Stratakis, M.D.

STUDY TITLE: Clinical and Molecular Analysis of ACTH-Independent Steroid Hormone Production in Adrenocortical Tissue

Latest IRB Review: Continuing Review 7/23/04

Latest Amendment Approved: Amend D 4/8/03

Linkage Study Assent

Your parents have contacted the National Institutes of Health, because you or one of your relatives has a tumor in one of the glands in your body called the "adrenal gland". The cause of the tumor is unknown, but in some cases it runs in families ("is inherited"). Read this paper and ask us questions about anything you do not understand. Then you and your parents decide if you wish to take part.

What we want to do

The purpose of this study is to find out what causes adrenal gland tumors. To do this, we need blood from members of families in which someone has this disease. We will use these samples to extract DNA. DNA is the substance that contains the genes that determine inheritance among people that belong to a family. We will compare the DNA from various family members to see if we can find something in common among the people who have tumors. This information will help us and other investigators to find the gene that caused these tumors.

You will probably only need to see us or your family physician or pediatrician once to complete this study.

What we want you to do

(1) Your parents and your pediatrician will need to tell us about any medical problems you may have. Anything they tell us will be kept private.

(2) We will need to examine your blood. To get the blood, we will stick a needle into your arm and take a small amount of blood (2 to 4 teaspoons) through the needle. That will only hurt for a minute. Then it will stop hurting. We will put a special cream on your arm called EMLA one hour before drawing blood to help blood drawing so that it doesn't hurt. The blood will be tested for your genes.

We will tell you and your parents what we find. If you don't want to know about what we find, just tell us.

What you have to decide about

We want you to understand what we do, why we do it, and the things that will hurt. Please ask us, if there is anything you do not understand now or later.

If you agree to have the blood test, we will ask you to write your name on this piece of paper, beside the X. Signing your name on this piece of paper is the way of showing that you agree. You do not have to do this, if you or your

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parents do not want to. Do not write your name until you feel you understand what will happen. Even if you agree now, you and your parents can change your minds later. Just tell us that you do not wish to take part any longer, and we will stop.

I have had this study explained to me in a way that I understand, and I have had the chance to ask questions. I agree to take part in this study.

Signature of Minor Patient: _____ Date: _____

Signature of Investigator: _____ Date: _____

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